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Intravitreal Ranibizumab (LucentisTM) Plus Verteporfin Photodynamic Therapy for Neovascular Age-related Macular Degeneration: FOCUS 2-year Results

Andrew N. Antoszyk, MD (Charlotte, NC),* Debbi Kotlovker, (San Francisco, CA),* Sharon O'Byrne, (San Francisco, CA)*

PURPOSE
The 2-year FOCUS study compared the safety and efficacy of monthly intravitreal injections of ranibizumab (Lucentis) in combination with verteporfin (Visudyne®) photodynamic therapy (PDT) vs. PDT alone in patients with subfoveal, predominantly classic choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD). PDT was performed at study start and then as needed.

METHODS
In this Phase I/II, multicenter, randomized, single-masked, controlled study, patients received monthly intravitreal injections of ranibizumab (0.5 mg; n=105) or sham injections (n=56). PDT was performed 7 days before initial ranibizumab or sham treatment and then every 3 months as needed. The primary efficacy endpoint was the proportion of patients who at 12 months had lost less than 15 letters from baseline bestcorrected visual acuity, measured using ETDRS charts. Morphologic changes in the CNV lesion were assessed by fundus photography and fluorescein angiography. Safety evaluation included ocular and nonocular adverse event monitoring.

RESULTS
In the primary analysis at 12 months, 95 of 105 (90.5%) ranibizumab-treated patients had lost less than 15 letters from baseline visual acuity, vs. 38 of 56 (67.9%) PDT alone patients (P=.0003). Also, 25 (23.8%) ranibizumab-treated patients had gained 15 or more letters, vs. only 3 (5.4%) PDT alone patients (P=.0033). During the first study year, the key ranibizumab associated serious ocular adverse events were intraocular inflammation (12 patients; 11.4%) and endophthalmitis (2 patients [1.9%]; 5 patients [4.8%] if presumed cases included). Key serious nonocular adverse events included myocardial infarctions in the PDT alone group (2 patients [3.6%]; 0 patients in the ranibizumab group) and cerebrovascular accidents in the ranibizumab group (4 patients [3.8%]; 0 patients in the PDT alone group). Cumulative 2-year efficacy and safety results will be presented.

CONCLUSION
At 1 year, ranibizumab plus PDT was more effective than PDT alone in treating predominantly classic neovascular AMD. It is unclear if this superiority was due to combination treatment or to ranibizumab. Ranibizumab increased the risk for serious intraocular inflammation, but affected patients still benefited visually on average. Results through the second study year will be presented.

* Financial interest disclosed